

AMENDMENT AND RESPONSE

Serial Number: 09/345,815

Filing Date: June 30, 1999

Title: METHOD FOR INHIBITING C-JUN EXPRESSION USING JAK-3 INHIBITORS

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paragraph. The amendments were not made to avoid prior art. Thus, the Amendments do not create estoppel which would limit the claims. Accordingly, Applicant is entitled to a full range of equivalents upon issuance of the instant claims.

The amendments to claim 4 are supported by originally-filed claim 4; the amendments to claim 5 are supported by the specification at page 6, lines 5-7; the amendments to claims 10, 11, 12 and 13 are supported by originally-filed claims 10, 11, 12 and 13, respectively; and new claim 15 is supported by originally-filed claims 1 and 9 and by the specification at page 6, lines 8-12 and page 9, line 26 through page 10, line 14.

At page 4 of the Office Action, the Examiner requested that Applicant clarify the citizenship of the Inventor. The Declaration, which was mailed on September 8, 1999 and signed by the inventor, Fatih Uckun, identifying the citizenship of the inventor as the United States is correct. Thus, an appropriate and correct Declaration signed by the inventor has been filed with the U.S. Patent and Trademark Office.

Also at page 4 of the Office Action, the Examiner objected to the drawings alleging that they are incorrectly referenced in the description. Applicant has amended the drawings herein to correct a typographical error. The label on previous Figure 1 should have read Figure 4, previous Figure 2 should have read Figure 1, previous Figure 3 should have read Figure 2, and previous Figure 4 should have read Figure 3. It is submitted that the correct numbering for the figures would have been clear to one skilled in the art from the brief description of the drawings found at pages 6-8 of the specification. Thus, no new matter has been added by way of this amendment.

The Examiner objected to claim 5 because the claim language of claim 5 is identical to claim 4. The amendments to claim 5 renders the Examiner's objection to claim 5 moot.

Applicant hereby affirms the election of Restriction Group III, drawn to the use of a quinazoline compound of formula I to inhibit the activation of c-jun.

35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner rejected claim 1 under 35 U.S.C. § 112, second paragraph, as being incomplete. The Examiner also rejected claims 4 and 5 under U.S.C. § 112, second paragraph, as being unclear. The cancellation of claim 1 and the amendments to claim 5 render the Examiner's rejections moot. It is respectfully submitted that the pending claims are in conformance with 35 U.S.C. § 112, second paragraph. Therefore, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 112, second paragraph, rejection of the claims.

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35 U.S.C. § 102(b) Rejection

The Examiner rejected claims 9 and 10 under 35 U.S.C. § 102(b) as being anticipated by Myers et al. (Bioorganic & Medicinal Chemistry Letters, 7, 417 (1997)). This rejection, insofar as it may be maintained with respect to the pending claims, is respectfully traversed.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent, a single prior art source must contain all its elements, Hybritech Inc. V. Monoclonal Antibodies, Inc., 231 USPQ2d 90 (Fed. Cir. 1986). There must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the art. Scripps Clinic & Res. Found v. Genentech, Inc., 18 USPQ2d 1001 (Fed. Cir. 1991).


Myers et al. disclose preliminary results of a SAR study of quinazoline-based inhibitors of p56^{lck} and EGF-R tyrosine kinase activity. The authors summarize their results by concluding that compound 10 (RPR-108518A) is a moderate nonselective inhibitor of p56^{lck} tyrosine kinase (page 420).

The instant claims are directed to a method for inhibiting c-jun activation in mammalian or avian cells comprising contacting the cells with an effective inhibitory amount of a quinazoline compound of formula I. The instant claims are not directed to compounds *per se*. Myers et al. do not teach or suggest a method of inhibiting c-jun activation. Furthermore, Myers et al. do not disclose or suggest a method of inhibiting c-jun activation with a quinazoline compound. Moreover, Myers et al. do not teach or suggest a method of inhibiting c-jun activation with the use of a quinazoline compound of formula I. Therefore, the disclosure of Myers et al. does not anticipate Applicant's claims. Hence, withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. § 103(a) Rejections

At page 6 of the Office Action, the Examiner rejected claims 1, 4-5, and 11-13 under 35 U.S.C. § 103(a) as being unpatentable over Karin et al. (Current Opinion in Cell Biology, 9, 240 (1997)) in view of Riedy et al. (Genomics, 37, 57 (1996)) and Chae et al. (Cancer Research, 53, 447 (1993)). As these rejections may be maintained with respect to the pending claims, they are respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference



teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success, i.e., that the use a quinazoline compound of formula I will inhibit c-jun activation. Finally, the prior art reference must teach or suggest all the claim limitations (In re Ochiai, 37 USPQ2d 112 (Fed. Cir. 1997)). (When evaluating the scope of a claim, every limitation in the claim must be considered.) (MPEP § 2143). The teaching or suggestion to arrive at the claimed method and reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (MPEP § 2143 citing with favor, In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991)). Applicant respectfully submit that the Examiner has not established the *prima facie* obviousness of the present claims.

Karin et al. is a review which generally discloses the function and regulation of AP-1, a dimeric family of transcription factors consisting of Jun, Fos, or activating transcription factor (ATF). Specifically, Karin et al. disclose the regulation and function of *c-fos*, *c-jun*, and ATF2 genes. Additionally, Karin et al. disclose the regulation of Jun activity by interacting proteins and the possible role of AP-1 in apoptosis.

Karin et al. do not disclose any quinazoline compounds or suggest that any quinazoline compounds are useful to inhibit c-jun activation. As such, Karin et al. provide no motivation to inhibit c-jun activation with a quinazoline based compound of formula I as recited by the instant claims. Additionally, Karin et al. would not provide a reasonable expectation that a compound of formula I could inhibit c-jun activation.

The secondary references, Riedy et al. and Chae et al., also do not disclose quinazoline based compounds or suggest that any quinazoline compounds are useful to inhibit c-jun activation. Thus, neither Riedy et al. nor Chae et al. provide motivation to inhibit c-jun activation with a quinazoline based compound of formula I as recited by the instant claims. Additionally, neither of the secondary references would provide a reasonable expectation that a compound of formula I could inhibit c-jun activation. Thus, Riedy et al. and Chae et al. do not remedy the deficiencies of the primary reference Karin et al. Therefore, the methods recited by the instant claims are not *prima facie* obvious over Karin et al. in view of Riedy et al. and Chae et al.

Additionally, at page 8 of the Office Action, the Examiner discussed Rosette and Karin, Science, 274, 1194 (1996). Again, as discussed above, Karin et al., Riedy et al., and Chae et al. do not disclose quinazoline compounds or suggest that any quinazoline compounds are useful to inhibit c-jun activation. They also do not provide motivation to inhibit c-jun activation with a quinazoline based compound of formula I as recited by the instant claims. Nor do they provide a reasonable expectation that a compound of formula I could inhibit c-jun activation. Rosette et al.

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do not remedy the deficiencies present in the combination of the primary and secondary references. Thus, Rosette et al. do not render the instant claims *prima facie* obvious.

At page 9 of the Office Action, the Examiner rejected claims 9-10 under 35 U.S.C. § 103(a) as being unpatentable over Karin et al. in view of Myers et al. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

As discussed above, Karin et al. do not disclose quinazoline based compounds or suggest that any quinazoline compounds are useful to inhibit c-jun activation. As such, Karin et al. provide no motivation to inhibit c-jun activation with a quinazoline based compound of formula I as recited by the instant claims. Additionally, Karin et al. would not provide a reasonable expectation that a compound of formula I could inhibit c-jun activation. Thus, Applicant's invention is not rendered obvious by Karin et al.

Also as discussed above, Myers et al. disclose quinazoline based compounds in the context of a SAR study of quinazoline based inhibitors of p56^{lck} and EGF-R tyrosine kinase activity. Myers et al. do not teach or suggest that the compounds disclosed therein are useful to inhibit c-jun activation. Nor do Myers et al. provide a reasonable expectation that a compound of formula I could inhibit c-jun activation. Additionally, Myers et al. provide no motivation to inhibit c-jun activation with a quinazoline based compound of formula I as recited by the instant claims. Thus, Myers et al. do not remedy the deficiencies of the primary reference Karin et al. Therefore, the methods recited by the instant claims are not *prima facie* obvious over Karin et al. in view Myers et al.

Based on these remarks, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 103(a) rejections.

Conclusion

Applicant believes that the claims (4-5, 10-13, and 15) are in condition for allowance and respectfully requests reconsideration of the application and allowance of the

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claims. The Examiner is invited to telephone the below-signed attorney at (612) 359-3265 to discuss any questions which may remain with respect to the present application.

Respectfully submitted,

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Date 27 April 2000

By 

Robert J. Harris, Ph.D.
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, D.C. 20231 on April 27, 2000.

Jane Brodtschink
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Signature